# Plain Talk About Childhood Immunizations



## Special Acknowledgment

We would like to thank the many parents and health care professionals who volunteered their time and input to help make this a useful and accurate booklet for all Alaska families.

#### Thank You.

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## 1. A Message to Parents

Thank you for your interest in finding out more information about immunizations. As parents, we are asked to make many important decisions concerning our children. Some of the most difficult decisions can be in regard to their health care. For most, to have your child immunized is one of the easiest decisions. For others, it is more difficult. We all want to make the right choices and do what is best for our children. As a community, we also need to protect the public's health. We recommend that you have your child immunized, but ultimately the decision is yours.

We designed this booklet in response to requests by parents, health care professionals, school nurses, child care providers and others to:

- provide more information about immunizations and vaccinepreventable diseases, much in the same way you look for information on car seats, bicycle helmets, and age-appropriate toys;
- provide balanced information about the benefits and risks of vaccination and assist you in making an informed decision;
- respond to inaccuracies or misinformation about immunizations and vaccine-preventable diseases.

We have arranged the information so you can read each section independently. We use a question and answer format in many areas, but may not have included all the answers you need. We encourage you to discuss these issues with a health care professional or your local health department.



## 2. The Facts About Vaccine-Preventable Diseases

#### MEASLES, MUMPS, & RUBELLA (MMR)

Click here for pictures

Measles, mumps and rubella are all viruses that spread from person to person **very** easily through coughing, sneezing, or just talking.

**Measles** causes a high fever, rash, and cold-like symptoms. It can lead to hearing loss, breathing problems, brain damage, and even death. Measles spreads so easily that a child who has not been immunized will most likely get the disease if exposed to it. In fact, studies have shown that the measles virus can remain in the air (and be contagious) for up to two hours after a person with the disease has left the room.

**Mumps** causes headache, fever, swelling of the cheeks and jaw, and swelling of the testicles in adolescent and adult males. It can lead to hearing loss, meningitis (inflammation of the brain and spinal cord) and brain damage.

**Rubella** (German Measles) causes a slight fever and a rash on the face and neck; rubella is usually a mild disease in infants and children. However, pregnant women who get rubella can lose their babies, or have babies with severe birth defects (known as "Congenital Rubella Syndrome") like hearing loss, cataracts on the eyes, heart defects and mental retardation.

#### DIPHTHERIA, TETANUS, & PERTUSSIS (DTP/DTaP) Click here for pictures

**Diphtheria**, which is easily spread through coughing or sneezing, is caused by a toxin from diphtheria bacteria. Diphtheria can cause paralysis, breathing and heart problems, and death.

**Tetanus** ("lockjaw") is caused by the toxin produced by tetanus bacteria and occurs when a tetanus germ enters a cut or wound. It can cause painful tightening of the muscles (usually all over the body), breathing and heart problems, and death. **Three out of 10 people who get tetanus die from the disease.** 

**Pertussis** ("whooping cough"), also caused by a bacteria that is spread through coughing or sneezing, causes very long spells of coughing that make it hard for a child to eat, drink, or even breathe. These attacks can last for weeks. Pertussis can cause lung problems, seizures, brain damage and death, especially in infants under 1 year of age. **Click here for video** 

#### POLIO Click here for picture

**Polio** causes fever and may progress to meningitis and/or lifelong paralysis. Polio can be fatal. Persons infected with the poliovirus shed the virus in their stool and can transmit the virus to others.

#### HAEMOPHILUS INFLUENZAE TYPE B ("Hib") Click here for picture

**Hib disease** can cause infections of the joints, skin and blood, meningitis (inflammation of the brain and spinal cord), brain damage and death. Before the introduction of effective vaccines, *Haemophilus influenzae* was the leading cause of bacterial meningitis among children under 5 years of age. This bacterial disease is most serious in infants under one year of age. Despite receiving appropriate medical care, 2 to 5 of every 100 children infected with Hib die. For children who survive, 15-30% have lingering brain damage or other serious health problems.

#### **HEPATITIS A** Click here for picture

**Hepatitis A** is a serious viral infection of the liver that causes fever, jaundice (yellow skin and eyes), loss of appetite, and nausea. It is spread from person-toperson. You also can catch it by eating food (including shellfish from polluted water) or drinking water that has been contaminated with fecal material from a person infected with the hepatitis A virus. **Hepatitis A infection is a major health problem in Alaska**; **in 1993, four Alaskans died from this disease.** 

#### **HEPATITIS B** Click here for picture

**Hepatitis B** is also a serious disease of the liver which is caused by a different virus than hepatitis A. It can be passed from an infected mother to her newborn during childbirth and from one person to another through blood or body fluids or by sexual contact. A lifelong infection with this virus can cause liver cancer and death. In fact, the earlier in life a person is infected with hepatitis B, the more likely he or she is to become a lifelong carrier of the disease and to pass it on to others.

#### VARICELLA ("Chickenpox") Click here for picture

Varicella is a very contagious viral disease that causes rash and fever. It is spread by coughing and sneezing or direct contact with drainage from the rash. Among children, bacterial infection of the skin lesions is a common complication. The disease is usually mild and symptoms last only a few days, but in rare cases it can lead to serious complications such as encephalitis, pneumonia and even death. It is more serious in adults and persons with impaired immune systems. If a woman gets chickenpox while pregnant, it can cause birth defects or the death of her baby. In addition, varicella virus remains "hidden" in the body after infection and may become reactivated into herpes zoster ("shingles") later in life. In the United States, about 100 people per year die from complications of chickenpox disease

#### **Proper Immunization Saves Lives**

Immunization is one of the greatest medical success stories in human history – and has saved millions of lives in the 20<sup>th</sup> Century.

Many serious childhood diseases are **preventable** by using vaccines routinely recommended for children. Since the introduction of these vaccines, rates of diseases such as polio, measles, mumps, rubella, diphtheria, pertussis (whooping cough), and meningitis caused by *Haemophilus influenzae* type b have declined by 95% to 100%. Prior to immunization, hundreds of thousands of children were infected and thousands died in the U.S. each year from these diseases. In underimmunized populations of the world, 600,000 children die each year from pertussis (whooping cough), and over 1,000,000 children per year die from measles.

The 1989-1991 measles epidemic in the United States was responsible for over 55,000 cases and more than 120 deaths. Nearly half of these deaths were in children under the age of 2.

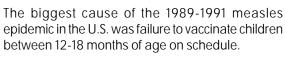
Without immunizations, the diseases from which we are now protected will return to sicken and even kill many infants and children. Many of the children who survive could suffer from health problems for the rest of their lives.

#### **Immunizations Prevent the Spread of Disease**

Diseases spread through communities by infecting unimmunized people as well as the small percentage of people for whom an immunization did not work. Individuals who are unimmunized increase the risk that they, and others in their community, will get the diseases vaccines can prevent. For some highly contagious diseases, such as measles, even a small number of unimmunized or underimmunized people can lead to an outbreak.

During the years 1986 through 1990, an average of 29 cases of Hib meningitis were reported yearly in Alaska. From 1991 to 1995, after Hib vaccine became

available throughout the state, an average of only 4.6 cases were reported each year.



In 1998, all of the measles outbreaks in the U.S. could be traced to people who came from other countries. Dangerous infectious diseases largely under control in the U.S. are *"only a plane ride away,"* so everyone must remain protected by being immunized.



#### **Immunizations are Safe**

As a result of medical research and ongoing review by doctors, researchers, and public health officials, vaccines are extremely safe and getting safer and more effective all the time. Immunizations are given to keep healthy people well, so they are held to the highest safety standards (see Chapter 8: Vaccine Safety).

#### **Immunizations Save Money**

Every dollar spent on vaccine saves at least \$7 in medical costs and \$25 in the overall costs related to vaccine-preventable diseases.

The estimated direct medical cost of the 1989-1991 measles outbreak in the U.S. was over \$150 million. This does not include the indirect costs to the family, such as lost days of work, school and child care.

Current estimates of direct medical costs and indirect (work loss) costs of hepatitis B related liver disease exceed \$500 million annually.

#### And, Did you Know...

Childhood vaccines are free at most clinics in Alaska. (Some private providers
may charge a small administrative fee to cover their costs of giving the
shots, but vaccines themselves are free.)

Children need the majority of their immunizations in the first two years of their lives, when they are most vulnerable to vaccine-preventable diseases.

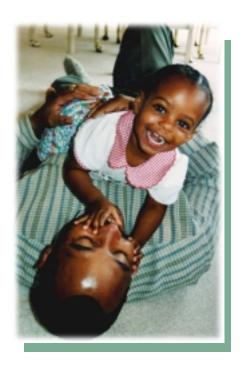
 Immunizations work by using the natural power of the body's own immune system to develop defenses against diseases.

An infant's immune system cannot easily fight off disease-causing bacteria or viruses. While breastfeeding can help to prevent some diseases among babies, it is not effective in preventing the serious diseases that immunizations do. Of the 4 cases of Hib meningitis reported in Alaska in May, 1996, all were in infants less than 7 months of age. Often, the effects of disease are more serious in infants than in older children. There are no effective alternatives to immunization for protection against these serious and sometimes deadly infectious diseases.



• A disease currently may not be present in a community, but disease outbreaks can and do occur in communities that are not completely protected. In spring, 1996, 63 cases of measles occurred during an outbreak in Juneau; this was more than twice the number of cases reported in Alaska during the previous five years combined. These 63 cases gain even more significance when compared with the rest of the country. Although Alaska has less than 0.5% of the country's population, the state accounted for 16% of all U.S. measles cases in 1996. And the thirty-three cases of measles reported in Anchorage during an outbreak in 1998 represented one-third of all measles cases in the U.S. that year.

"Some parents feel that these diseases are from the distant past, and we don't have to worry about them anymore," states Dr. Jim Raelson, a pediatrician at Alaska Native Medical Center. "However, as recently as 10 years ago, I cared for a significant number of children every year who either died or were severely affected by hepatitis B and Hib disease. [Vaccine-preventable] diseases are more rare now in Alaska [due to vaccines], but we know that the germs are still waiting for the unprotected child."



# 3. The Immune System and How Vaccines Work

The immune system is the defense mechanism in each person that helps the body fight disease. Medical science has found an effective way to help the immune system fight disease through the use of vaccines.

When you get an infection, your body reacts by producing substances called antibodies. These antibodies fight the foreign substance (antigen) or disease and help you get over the illness. The antibodies usually stay in your system even after the disease has gone and protect you from getting the same disease again. This is called *immunity*.

Newborn babies often have immunity to some diseases because they have antibodies that they received from their mothers during pregnancy or through breastfeeding. But this immunity is only temporary. By immunizing our children, we can help them remain immune to many diseases, even after they lose their mothers' antibodies.

Vaccines make the body think it is being invaded by a specific disease, and the body reacts by producing antibodies. Then, if the child is exposed to the disease in the future, he or she is protected. Even in the rare instances that a vaccinated child gets a vaccine-preventable disease, the symptoms are usually much less severe, and the child recovers more quickly than if he or she had not been vaccinated.

Some vaccines consist of weakened disease virus. These vaccines (measles vaccine, for example) are extremely effective with only one or two doses. Some other vaccines are made of inactivated, or "killed", virus or bacteria (like the injectable polio vaccine, "IPV") and require multiple doses to build up the immune response. Some inactivated vaccines, like the vaccine against tetanus and diphtheria, require booster doses throughout life.

•••••

## QUESTION: Do vaccines decrease the immune system's natural ability to fight disease?

**ANSWER:** No. A vaccine produces an immune response that is very specific to the organism or antigen which produced it. For example, the antibodies produced in response to measles virus have no effect on the body's ability to respond to another illness, such as varicella (chickenpox).

## QUESTION: I heard that the less you "bombard" the immune system at one time, the better, so you should not give several vaccines on the same day. Is this true?

**ANSWER:** No. A child's body is not harmed by receiving more than one childhood vaccination at the same time. While there is much more to be learned about the immune system, there are some things we do know. Scientific data show that giving a child many vaccines at the same time has no adverse effect on a normal immune system.

According to William Atkinson, MD, U.S. Centers for Disease Control and Prevention, "The immune system is an extremely capable system. It can manage and respond to literally millions of antigens (foreign substances) at the same time. Take for example, walking outside on a spring day with flowers and trees in bloom. Through your mouth, nose and lungs, your immune system will constantly respond to multiple antigens (like pollen and dust) as it does its work in your bloodstream. In the same way, in daily interactions, you may be exposed to multiple cold viruses and your body will respond successfully. But the immune system needs help to ward off the serious infectious diseases that immunizations can prevent."

#### QUESTION: Is the method of injecting vaccines harmful for the body?

**ANSWER:** No. Just as the method of injecting valuable medicines for illness is okay, it also is safe to inject vaccines. Vaccines are not injected directly into the bloodstream; most vaccines are injected into muscle or fat, or just below the skin. In addition, the syringe and needle used for a vaccination are sterile. They are used only once and then thrown away, so there is no possibility for the spread of bloodborne diseases.

## QUESTION: I've heard that some people who get these diseases had been vaccinated against them - how could this be true?

**ANSWER:** Modern vaccines are extremely effective, but they are not perfect. For example, a vaccine that is 90% effective means that one in every ten people who is vaccinated is not actually protected from the disease. (For reasons related to the individual, not all vaccinated people develop immunity.) Should a disease affect such a community, those who are unprotected are likely to be infected – which includes those who were not vaccinated and the 10% of people who were vaccinated but in whom the vaccine did not work. Because most diseases that vaccines prevent are transmitted from person to person, the more people in a community who are immunized, the less likelihood there is that disease will be transmitted and "find" the few who are unprotected.

Finally, most vaccines require more than one dose to reach the maximum amount of immunity, and as mentioned above, some require booster doses throughout life to continue that immunity.

QUESTION: I heard that because of better hygiene and sanitation, vaccinepreventable diseases began to disappear before vaccines were introduced. Is this true?

**ANSWER:** Yes. Most infectious diseases became less common as living conditions and hygiene improved. However, they remained as serious threats. It often takes a combined approach to effectively combat disease. Several factors have helped the work of vaccines in preventing disease, including:

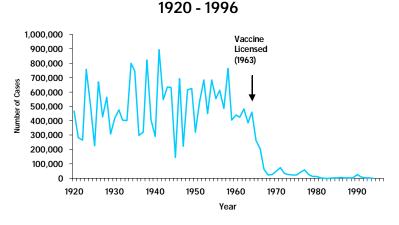
- better nutrition;
- less crowded living conditions and better sanitation;
- the development of more effective antibiotics and other medical treatments.

In spite of these advances, vaccine-preventable disease outbreaks still occur because of lack of vaccination or under-immunization. Diseases like measles and pertussis are highly contagious, regardless of hygiene and living conditions.

"As a lifelong resident of the Bristol Bay region, I have personally seen vaccines prevent infectious diseases," states H. Sally Smith, Chairman of the Board, Bristol Bay Area Health Corporation. "I encourage parents to protect their children's health with vaccinations."

Looking at the actual number of cases of disease over the years can leave little doubt of the significant direct impact vaccines have had, even in modern times. The number of cases of measles, pertussis, *Haemophilus influenzae* type b (Hib) and other vaccine-preventable diseases has decreased dramatically since the introduction of vaccines against these diseases. For example, Figure 1 shows the reported number of cases of measles from 1920 to the mid-1990's. There were periodic peaks and valleys throughout the years, but the real, permanent drop coincided with the licensure of measles vaccine in 1963.

Figure 1. Reported Measles Cases in the United States,



A more recent example of the significant impact that vaccines have had is illustrated by the vaccine against *Haemophilus influenzae* type b (Hib). Once a leading cause of death among young children, Hib disease has dropped more than 95% in the last five years. Sanitation is not that much better now than in the early 1990's; clearly, sanitation alone cannot account for the dramatic drop in Hib disease.

## QUESTION: Since vaccine-preventable diseases have been almost eliminated from the United States, do I still need to vaccinate my child?

ANSWER: Yes. Although it's true that vaccination has enabled us to reduce most vaccine-preventable diseases to very low levels in the United States, some of these diseases are still quite common, even epidemic, in other parts of the world. Travelers can unknowingly bring these diseases into Alaska. If we are not protected by vaccinations, these diseases could quickly spread throughout the population and cause epidemics here. For example, the 1998 measles outbreak in Anchorage, Alaska, was begun by an infected child visiting from Japan.

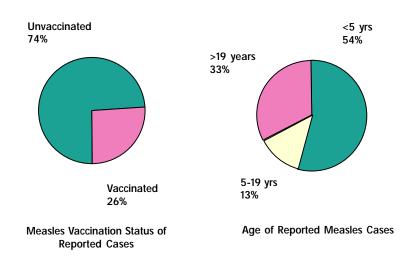
We should still be vaccinated, then, for two reasons:

- To protect ourselves. Even if we think the chances of our child getting any of
  these diseases is small, the diseases still exist and can still infect anyone
  who is not protected. A few years ago in California, a child who had just
  entered school caught diphtheria and died. He was the only unvaccinated
  pupil in his class.
- To protect those around us. There are a small number of people who cannot be vaccinated (because of severe allergies to vaccine components, for example) and a small percentage who do not respond to the vaccine (for reasons related to those individuals). These people are susceptible to disease, and their only hope of protection is that people around them are immune and cannot pass the disease along to them. We would think it irresponsible of a driver to ignore all traffic regulations on the presumption that other drivers will watch out for him. In the same way, we shouldn't rely on people around us to stop the spread of disease without doing what we can as well.



Figure 2 illustrates an outbreak of measles that began in Ketchikan, Alaska, in 1990. The majority of the cases in this outbreak were in pre-school aged children who were infected with the measles virus at their day care centers or in medical settings. Nearly three-fourths of the people infected with measles during this outbreak were unvaccinated.

Figure 2. Measles Outbreak in Ketchikan, Alaska, 1990 (N = 80)





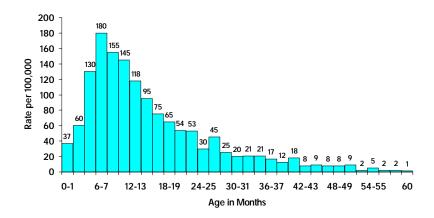
## 4. To Wait or Not to Wait

QUESTION: Is it okay to wait until my child is getting ready to start school to get his or her immunizations?

**ANSWER:** No. Waiting until kindergarten, or even until after your child's first birthday, to have your child immunized can put him/her at increased risk of contracting serious diseases that could be prevented. Maternal antibodies that your child may have received during pregnancy begin to fade during his or her first year of life. At the same time, young children are also more frequently exposed to other children and adults who may be carrying these diseases.

Finally, most of these diseases are more dangerous in infants and very young children. For example, Hib meningitis most often attacks infants between 6 and 18 months of age, as shown in Figure 3. Likewise, pertussis is most severe in infants less than 1 year old. Postponing your child's immunizations reduces their benefit to your child and leaves him/her at risk of getting these serious diseases.

Figure 3. Rate of Hib Disease in the United States, by Age Group - 1996



#### QUESTION: Can my child catch-up if she is behind in immunizations?

**ANSWER:** Yes, but it is best to stay as close as possible to the recommended immunization schedule. Until the entire vaccine series is received, the individual will not have the maximum amount of protection against the disease. If a child is behind on the immunization schedule, a catch-up schedule can be determined by the child's doctor, nurse, or clinic. **An interruption in the schedule does not require a child to start the series over.** 

#### QUESTION: Are immunizations okay even if my child has a minor illness?

**ANSWER:** Immunizations can be given and should be requested during any visit to your doctor or nurse, even if your child has a minor illness (such as mild fever, a cold, or diarrhea) or is taking antibiotics. The vaccine will still be effective and it will not make your child's illness worse. Receiving all immunizations when they are due is an important way to complete each vaccine series on time and prevent extra visits.

#### QUESTION: Are there times that vaccines should NOT be given?

**ANSWER:** Yes, sometimes there are medical reasons for not giving a vaccine or for delaying it. These are referred to as "contraindications" and "precautions".

In general, a child should not receive a vaccine if he or she:

- has a condition that is likely to result in a serious medical or life-threatening problem if the vaccine were given, or
- has a condition (such as severe illness) which could reduce the ability of the vaccine to produce the desired immunity.

#### Examples:

- A child is allergic to a vaccine component (e.g., neomycin) that could cause an allergic response, such as difficulty breathing, low blood pressure or shock.
- A child has recently received blood products (such as immune globulin or a blood transfusion) or has a moderate or severe illness.

In most instances, factors such as breastfeeding, ear infections, antibiotic treatment, mild diarrhea and milk allergy do not contraindicate vaccine use. Check with your health care provider if you have specific questions regarding these or other circumstances.



# 5. Questions and Answers About Specific Vaccines

#### HEPATITIS A

QUESTION: Is it true that only people who live in small villages with no sewer system are at risk of getting hepatitis A?

**ANSWER:** No. Hepatitis A, like other contagious diseases, "looks for" people that are not protected from the disease, no matter where they live. For the past 25 years, public health officials have tried to reduce the impact of this serious disease in Alaska. In spite of these efforts, Alaska historically has had major hepatitis A outbreaks every 5 to 7 years. In 1993, four people in Alaska died from hepatitis A infection. All Alaska children between the ages of 2 and 18 years should receive the hepatitis A vaccine that protects against the serious liver infection caused by the hepatitis A virus. It is an extremely safe and effective vaccine with very few side effects, and it only requires two doses.

"We now have a safe and effective vaccine against hepatitis A," says Dr. John Middaugh, Chief of the State of Alaska Section of Epidemiology. "At last, we can protect our children and prevent future outbreaks of this disease. All Alaskan children should be vaccinated."

#### HEPATITIS B

QUESTION: Why is it recommended that the hepatitis B vaccine series be started between birth and two months of age?

**ANSWER:** National immunization recommendations call for the routine immunization of all infants against hepatitis B because it is impossible to predict who will be at high risk for hepatitis B in the future. Approximately 30% of people who become infected with hepatitis B do not know how they got the disease. In addition:

- The earlier in life a child is exposed to the disease, the more likely it is that he
  or she will become a lifelong carrier. Hepatitis B immunization helps protect
  more people from becoming lifelong carriers.
- Hepatitis B virus infects 200,000 Americans annually; thousands of victims are adolescents and young adults. There is no specific treatment for acute hepatitis B. The virus can cause liver damage, liver cancer and death. Those who become lifelong carriers face significant health care problems and can infect others with the disease. In the U.S., more than 1.25 million people are chronically infected, and at least one-third of those were infected as infants or children.

 Unfortunately, vaccinating just "high-risk" individuals against hepatitis B has not proved to be an effective method for decreasing the incidence of this disease.

QUESTION: Does hepatitis B vaccine cause multiple sclerosis or Sudden Infant Death Syndrome?

ANSWER: No.

#### Multiple Sclerosis (MS):

Analyses by the World Health Organization, U.S. Institute of Medicine and the Medical Advisory Board of the National Multiple Sclerosis Society conclude that there is no evidence that the hepatitis B vaccine causes MS or other neurological diseases.

MS is an autoimmune disorder in which a person's antibodies attack the body's own myelin (the sheath that covers the nerves). MS is a life-long illness which fluctuates through periods of exacerbation (symptoms worsen) and remission (symptoms subside). The cause of MS is unknown, but the most widely held belief among medical experts is that patients are genetically at risk for the disease and some environmental factors can "trigger" the disease.

There is no evidence that hepatitis B vaccine increases the rate of MS in otherwise healthy individuals. A study by the French National Drug Surveillance Committee revealed that recipients of over 60 million doses of hepatitis B vaccine given between 1989-1997 were **less** likely to have neurological disease, including MS, than the general population. Hundreds of millions of persons worldwide have

been immunized with the hepatitis B vaccine without developing MS or any other autoimmune disease.

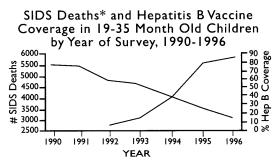
The National Multiple Sclerosis Society supports the wide and general use of hepatitis B vaccine.



#### Sudden Infant Death Syndrome (SIDS):

Since 1991, infants have been receiving hepatitis B vaccine starting as early as the first day of life. If SIDS were somehow related to hepatitis B vaccination, we would expect to see an increase in SIDS deaths since 1991. However, this is not the case. In fact, there has been a steady decrease in the numbers of newborn deaths as the number of hepatitis B vaccinations have increased (see Figure 4 below).

Figure 4. SIDS Deaths and Hepatitis B Vaccine Coverage in 19-35 Month Old Children, by Year of Survey, 1990-1996.



\* U.S. residents, NCHS annual mortality files

Almost all infants are vaccinated during the first year of life. Because vaccines are usually given at ages 2, 4 and 6 months, there is a considerable chance of **ANY** event or death occurring within 24 hours of vaccination by coincidence alone. Put another way, it is similar to saying that eating bread causes car crashes, because most car drivers who are in accidents could probably be shown to have eaten bread within the past 24 hours.

The Institute of Medicine reports: "All controlled studies that have compared immunized versus non-immunized children have found either no association... or a decreased risk... of SIDS among immunized children".



#### DIPHTHERIA, TETANUS AND PERTUSSIS

DTaP vaccine protects against diphtheria, tetanus and pertussis (whooping cough). Of these diseases, pertussis currently poses the most serious threat to infants and children in the United States. In the mid-1970s, two countries (Great Britain and Japan) cut back on the use of pertussis vaccine because of their concerns about the safety of the vaccine (see below for explanation). The effect was dramatic and immediate:

- In Great Britain, the drop in pertussis vaccination in 1974 was followed by an epidemic of more than 100,000 cases of pertussis and 36 deaths by 1978.
- In Japan, a drop in vaccination coverage from 70% to 20-40% led to a jump in pertussis from 393 cases and no deaths in 1974 to 13,000 cases and 41 deaths in 1979.

Of more immediate interest to Alaskans is the major epidemic of diphtheria which has been occurring for several years in the former Soviet Union. The decline in diphtheria vaccination rates of children and adults has resulted in an increase from 839 cases in 1989 to nearly 50,000 cases and 1,700 deaths in 1994. There already have been at least 20 cases of diphtheria imported from the former Soviet Union to Europe and 2 cases in U.S. citizens working in the former Soviet Union.

QUESTION: What is the difference between the old "whole-cell" DTP vaccine and the acellular pertussis vaccine (DTaP) currently in use?

**ANSWER:** The vaccine currently used against pertussis is known as "acellular" vaccine because it contains only the specific parts or products of the pertussis bacteria thought to be important for immunity. It differs from the "whole-cell" vaccine that was made from whole, killed pertussis organisms. Although it was effective, the whole-cell vaccine was associated with a higher frequency of local reactions (e.g., redness, swelling, pain at the injection site), fever, and, in rare instances, more severe side effects. Alaska providers now use only acellular (DTaP) vaccine.

A full series of DTaP shots protects approximately 80 out of 100 children exposed to the disease from getting severe pertussis (whooping cough). A full series of four DTaP shots by 18 months of age is recommended. This is important because:

- Children, especially young infants, who catch pertussis are often critically ill.
- There has been an alarming increase in pertussis cases in the United States, partly due to the spread of pertussis from young adults to insufficiently immunized infants.
- Most individuals who have had the full series of DTP or DTaP vaccine are protected from diphtheria, tetanus and severe pertussis for many years.

 Even children who do become ill with pertussis after vaccination with DTaP have a much milder illness than if they had not been vaccinated.

#### QUESTION: What are the side effects of DTaP vaccine?

**ANSWER:** The majority of children who receive DTaP vaccine will experience only minor soreness, swelling, and redness at the site of the injection. Some children also may have some fussiness, drowsiness, and/or loss of appetite. Usually these symptoms last only one to three days. Very rarely, a child will have a fever of more than 101 degrees (Fahrenheit), continuous crying for three hours or more, or convulsions or collapse, all followed by full recovery. In extremely rare instances, a very small number of children possibly could experience more severe side effects, such as long seizures or other brain disturbances (i.e., acute encephalopathy). Further doses of pertussis-containing vaccine would not be recommended for a child who experiences these severe side effects.

#### MEASLES, MUMPS AND RUBELLA

QUESTION: Is there any evidence to indicate an association between the MMR vaccine and autism?

**ANSWER:** No. The weight of reliable evidence does not support the idea that the MMR vaccine will increase the risk of developing autism or any other behavioral disorder.

The suggested link between autism or other behavioral disorders and the MMR vaccine was initially introduced by Dr. Andrew Wakefield of the Royal Free Hospital in the United Kingdom (U.K.). Dr. Wakefield's hypothesis suggesting that children experienced developmental problems shortly after receipt of MMR vaccine was based on research with only 12 children. Although many other studies have been conducted on this issue, none have confirmed Dr. Wakefield's theory.

According to the published results of a study of 498 autistic children over a 13-year period, also performed in the U.K. by Dr. Brent Taylor and colleagues, there is no association between MMR vaccine and autism. Typically, symptoms of autism begin to appear in children from 18-30 months of age. MMR vaccine is usually given to children at 12 to 15 months of age. Although autism may be detected during the weeks or months following MMR vaccination, this does not necessarily mean that the disorder was <u>caused</u> by the vaccine. Experts in behavioral and developmental disorders agree that autism is most likely a genetic disorder that occurs before birth, although research continues on its exact cause and cure.



#### **POLIO**

#### QUESTION: Is it still worth being immunized against polio?

**ANSWER:** Yes. Poliovirus is highly infectious. In fact, 90-100% of household contacts of an infected person will be infected with poliovirus. Polio is still a major public health problem in many countries of the world, and if children are not immunized, the disease could spread quite rapidly to the United States. Wild poliovirus disease has been eliminated from the United States since 1979 and the Western Hemisphere since 1991, and there are hopes for the total elimination of polio disease in the future. At that time, we may be able to stop polio vaccination. However, as long as polio exists in the world, our children need protection. One could say, *"Polio is just an airplane ride away."* 

#### QUESTION: Are there two different types of polio vaccine?

**ANSWER:** Yes. They are live oral polio vaccine (OPV) and inactivated polio vaccine (IPV). OPV was the vaccine of choice for routine immunization of most children in the United States from 1963 to the mid-1990's. However, as of January, 2000, an all-IPV immunization schedule is recommended for children in the United States.

#### QUESTION: Are there any risks associated with polio vaccine?

**ANSWER:** Yes. Oral polio vaccine (OPV) has been associated with a very rare occurrence of paralysis in vaccine recipients and their contacts. When OPV was the primary vaccine used in the U.S., there were approximately 8 cases of vaccine-associated paralytic poliomyelitis (VAPP) in this country each year. This represented **one case per 2.5 million doses given**. It was most likely to occur in persons with serious immune system diseases or with the first dose of vaccine.

Because of this <u>very</u> small risk associated with OPV, the inactivated polio vaccine (IPV), which is injected rather than taken orally, is now the only polio vaccine offered in the U.S. IPV protects a child from paralytic polio disease but eliminates the risk of VAPP. However, persons who are vaccinated with IPV can still "carry" the wild poliovirus in their bodies if exposed and pass it on to unvaccinated

household members through their stools. This is very unlikely to happen in the United States, where there has been no wild polio virus infection since 1979. However, OPV will continue to be used in some parts of the world where wild polio virus is still being spread.



#### **VARICELLA**

QUESTION: Chickenpox (varicella) isn't normally a very serious disease. Why vaccinate?

**ANSWER:** Although rare, complications from varicella disease such as pneumonia, encephalitis, "flesh-eating" bacterial infection, and death can occur in children and adults. Vaccinating against the illness during childhood will help reduce the incidence of the disease (and related complications) in later years. Additionally, it is hoped that varicella vaccine also will reduce the risk of "shingles", a painful nerve and skin disease caused by reactivation of the varicella virus later in life.

#### QUESTION: Does immunity from the varicella vaccine last?

**ANSWER:** Available data indicate that protection from varicella vaccine should last for <u>at least</u> 20 years. Experience with other live viral vaccines (like measles, mumps and rubella vaccine) has shown that post-vaccination immunity remains high throughout life. Studies are ongoing to determine how long protection is provided from varicella vaccine and whether booster doses may be needed in the future. However, even if an immunized individual develops chickenpox after being exposed to the disease, the illness will be much milder than if the person had never been vaccinated.



## 6. The Adolescent Health Visit: Shots Aren't Just Kids' Stuff!

Although immunization programs in the United States which focus on infants and children have greatly decreased the occurrence of many childhood infections, vaccine-preventable diseases such as hepatitis A and B, measles and rubella continue to affect adolescents and young adults.

In order to protect adolescents and young adults from these serious vaccine-preventable diseases, an *Adolescent Health Visit* at 11 to 12 years of age is strongly recommended. This visit will enable parents and their health care providers to discuss the recommended vaccines and decide which immunizations are needed. An Adolescent Health Visit also helps affirm a lifelong commitment to good health.

#### QUESTION: Which vaccines are recommended for my adolescent?

**ANSWER:** The recommended vaccines for adolescents are hepatitis A, hepatitis B, tetanus/diphtheria, and varicella. Also, if your child has not had a second dose of MMR (measles, mumps, rubella) vaccine, he or she will need it before entering school in Alaska. Contact your health care provider for information about scheduling your adolescent for these vaccinations.

#### **Immunizations Recommended for Adolescents:**



- Hepatitis A
- Hepatitis B
- Td (Tetanus/Diphtheria)
- Varicella (chickenpox)
- MMR (Measles/Mumps/Rubella)

# 7. Legal Requirements and Considerations

#### QUESTION: What are the legal requirements for immunizing children?

**ANSWER:** The legal requirements for childhood immunizations vary from state to state. In Alaska, the requirements are defined within regulations under the Department of Education and Early Development. Updated statutes and regulations (Alaska Administrative Code - AAC) are available at the Alaska Legislature's website: **www.legis.state.ak.us.** 

The regulations require the parents or guardians of each child being enrolled provide the childcare program or school with a copy of the child's immunization record which: (1) lists dates and dose numbers for each vaccine and (2) has been signed or stamped by a medical provider. These immunization records are updated by the doctor or nurse every time a child receives his/her vaccinations. It is important for the parents or guardians to keep these records of their child's immunizations.

To legally attend childcare (including Head Start Programs) or school, children must:

- be fully vaccinated for their age, or
- be in the process of catching up on late immunizations, or
- have a signed exemption from vaccinations for medical or religious reasons.



School immunization requirements in Alaska have nearly eliminated the transmission of vaccine-preventable diseases which, in the past, caused significant illness and death. Before immunization requirements for school and childcare attendance were strictly enforced, many Alaska children suffered from vaccine-preventable diseases. The effects of these vaccine-preventable illnesses ranged from minor inconveniences to death; at a minimum, they disrupted school and childcare attendance and caused logistical problems for parents. At the worst, they resulted in complications such as pneumonia, deafness, brain damage or even death. The goal of school and childcare immunization regulations is to assure that children in these settings receive maximum protection against these preventable diseases.

#### Immunizations aren't just the law...



they're part of a healthy life.

## 8. Vaccine Safety

Some parents have concerns about vaccine safety. In licensing vaccines, the U.S. Food and Drug Administration (FDA) has developed scientific criteria for approving vaccines and for monitoring side effects once approval has been given.

#### **Approval of Vaccines**

The approval process for a biological product such as a vaccine is based on federal regulations and involves clinical trials in three phases.

**Phase One:** Studies concerned primarily with learning more about the safety of the product.

**Phase Two:** Studies which usually are longer and involve more patients; designed to demonstrate the ability of a vaccine to induce the production of antibodies, as well as to further evaluate side effects and risks.

**Phase Three:** Studies involving a larger number of patients for longer time. They provide verification that a vaccine is effective in preventing a particular disease as well as information on risks vs. benefits.

After completing the three phases, the manufacturer submits the safety and effectiveness data to the FDA in an application for licensure to market the product. The FDA has the responsibility to review the clinical studies data, the facilities to be used and the methods to be used in the manufacture of the product for safety and effectiveness. On average, it takes over 5 years from the time of application for licensure until FDA approval of a product.

#### **Monitoring Vaccine Safety**

After a product is approved for marketing, the FDA continues to monitor the safety and effectiveness by various means, including on-site inspection of the manufacturing facility.

Additionally, the National Vaccine Adverse Events Reporting System (VAERS) is sponsored by the FDA and CDC. This system receives reports from providers, patients or parents regarding any possible adverse reaction that may have occurred after the receipt of any vaccine. Since 1988, health care providers who give vaccines and vaccine manufacturers have been required by law to report certain serious adverse events.

Other notable features of the vaccine monitoring system are:

• The U.S. FDA staff reviews manufacturers' vaccine lot (batch) tests and, as a protective measure, may repeat some of the tests themselves. After a vaccine lot release, the FDA conducts reviews of the weekly VAERS reports.

- A VAERS report does not mean the vaccine caused the adverse event. It only means the vaccination preceded the adverse event.
- Because VAERS information is limited to what is reported, it cannot establish causation. It can only look for trends and pinpoint the need to investigate further.
- The public should report any serious adverse event following any vaccine given. Report forms may be obtained by calling (800) 822-7967.

## QUESTION: Are certain vaccine lots associated with more adverse events than other lots?

**ANSWER:** Vaccine lots are closely monitored by the VAERS reporting system (see previous section). The FDA has the legal authority to recall a vaccine lot if the numbers of reports indicate that it is unsafe. There is no benefit to either the FDA or the manufacturer in allowing unsafe vaccines to remain on the market.

Occasionally, people have interpreted VAERS information incorrectly, which has led to unsubstantiated media reports about "unsafe lots" of vaccine. The VAERS system accepts all reports of any medical problems that have occurred following vaccination, sometimes as long as six months after administration. The VAERS system does not discard a report simply because it is unlikely to be caused by vaccination, nor does it discard a report because it is about a minor problem. For instance, if a person is vaccinated and has unrelated symptoms of illness one week later, the VAERS report would list that vaccine lot number. Vaccine lots vary by size; the larger lots are likely to receive more reports than smaller lots with fewer doses distributed. The fact that there are more reports does not mean that the lot is unsafe, or that the vaccine caused the problem.

#### **OUESTION:** How do we know VAERS works?

**ANSWER:** VAERS is an effective system for monitoring vaccine safety. Shortly after rotavirus\* vaccine became available in 1999, cases of bowel obstruction among some infants who had received the vaccine were reported to VAERS. Although these reports did not provide sufficient evidence to determine if there was a relationship between the vaccine and the bowel disorder, the CDC recommended that use of the rotavirus vaccine be suspended pending further evaluation. The CDC's actions were a direct result of the data obtained through VAERS.

In October 1999, the Advisory Committee on Immunization Practices (ACIP) recommended that rotavirus vaccine no longer be used because of the strong association between the bowel disorder and the vaccine. Medical experts agree that continued research is needed to clarify the relationship between the bowel disorder and the vaccine.

<sup>\*</sup>Rotavirus is the most common cause of severe diarrhea in infants and young children in the United States.

**QUESTION:** Do vaccines cause chronic disease, such as diabetes, Crohn's disease, and cancer?

**ANSWER:** After decades of vaccine use in the United States, available research shows no reliable evidence proving that vaccines cause chronic illness. Vaccine safety research, including research into theories linking vaccines to chronic diseases, is being conducted on a regular basis in the United States and overseas to assure that the public is receiving the safest possible vaccines.

Occasionally, researchers have published articles about their studies supporting theories about vaccines and chronic illness; however, when other researchers attempt to duplicate their results, they often cannot. Medical conclusions about vaccine safety and the causes of disease must be judged on the quality of the scientific research and evidence.





## 9. Compare the Risks

#### Risk of Disease and Serious Complications:

## *Haemophilus influenzae* type b (Hib disease):

Before Hib vaccine, 1 in 200 children developed meningitis or other invasive Hib disease by age five.

- 50% of cases in children less than one year old.
- Neurologic damage: occurs in 19 to 45 out of 100 children with invasive Hib disease.
- Death: 1 in 20 children with invasive Hib disease.

## Risk of Serious Reaction From Being Vaccinated:

#### **Hib Vaccine**

None reported to date.

#### **Diphtheria**

 $40\,\text{cases}$  in U.S. 1980-93. Due to decreased immunizations, 15,000 cases in Russia in early 1990s.

Death: 1 in 10

#### Tetanus:

50-100 cases per year in U.S., greater than 500,000 deaths per year worldwide.

Death: 1 in 3

#### Pertussis (whooping cough):

69% of all reported U.S. cases less than 5 years old, 45% in less than 12 month-old children. Many infants hospitalized.

- Pneumonia: 1 in 8.
- Convulsions/seizures: 1 in 100.
- Death: 1 in 500.

#### **DTaP Vaccine:**

**Diphtheria component:** None reported to date.

#### **Tetanus component:**

- Severe neuritis: 1 in 100,000.
- Severe allergic reaction: 1 in 1.000.000.

#### **Acellular Pertussis component:**

- Prolonged crying for 3 hours or more: 1 in 2000 children.
- High fever (greater than 105 degrees Fahrenheit), then full recovery: 1 in 3000 children.
- Limpness or paleness: 1 in 14,300 children.
- Convulsions or seizures: 1 in 14,300 children



## Compare the Risks

## Risk of Disease and Serious Complications:

#### Measles:

Prior to the introduction of vaccine, 400,000 reported cases per year. In 1989-91 epidemic: 55,622 cases due to large number of unimmunized children, 45% of cases were less than 5 years old; 20% hospitalized, 126 deaths.

Pneumonia: 1 in 17.

• Encephalitis (brain fever): 1 in 2,000.

Thrombocytopenia: 1 in 6,000.

Death: 1-2 in 1,000.

#### Mumps:

Cases: 3,000-5,000 per year.

• Encephalitis: 2 in 100,000.

Testicular swelling: 1-2 in 5 adults.

Deafness: 1 in 20,000.Death: 1-3 in 10,000.

#### Rubella:

12.5 million cases in 1964-65, 2,100 infant deaths, 11,250 fetal deaths, 20,000 cases of nervous system disorders.

Arthritis: 7 in 10 adult women.

Thrombocytopenia: 1 in 3,000.

 Congenital Rubella Syndrome: (deafness, cataracts, mental retardation) in 8 out of 10 infants if women are infected in early pregnancy.

## Risk of Serious Reaction From Being Vaccinated:

#### MMR Vaccine:

- Thrombocytopenia (bleeding tendency from decreased blood platelets): 1 in 30,000 to 40,000.
- Encephalopathy: less than 1 in 1 million doses administered.

#### Measles component:

 Severe allergic reaction: less than 1 in 1,000,000 people vaccinated.

#### Mumps component:

 Severe allergic reaction: less than 1 in 1,000,000 people vaccinated.

#### Rubella component:

- Arthritis (usually temporary):
   2-3 out of 10 adult women.
- Severe allergic reaction: less than 1 in 1,000,000 people vaccinated.



## Compare the Risks

## Risk of Disease and Serious Complications:

## Risk of Serious Reaction From Being Vaccinated:

#### **Hepatitis A:**

## Hepatitis A has been a large problem in Alaska; four deaths occurred here during an outbreak in early 1990s.

- Most common among school-aged children and young adults.
- Illness from hepatitis A can be mild, lasting 1 to 2 weeks, or severely disabling, lasting several months.

#### Hepatitis A Vaccine:

None reported to date.

#### **Hepatitis B:**

# Nine of 10 infants infected at birth will become lifelong carriers of the disease, and one out of four of these infants will ultimately die of liver failure. Estimated number of persons infected each year in U.S.: more than 100,000 people.

Hospitalizations per year: 15,000

Deaths: 5,900

#### **Hepatitis B Vaccine:**

 Severe allergic reaction: 1 in 600,000 doses administered.



## **Compare the Risks**

## Risk of Disease and Serious Complications:

#### Varicella (Chickenpox):

Varicella virus is extremely contagious. Nine out of 10 people in a household who have not had chickenpox already will catch the virus if exposed to an infected household member. Although usually quite mild, potential complications can include:

- Bacterial infection of skin lesions and scarring.
- Pneumonia.
- Hospitalization: 3 in 1000 cases.
- Death: 1 in 60,000 cases.
- 50-100 deaths per year in the U.S., mostly in healthy children and adults.
- Disease is more severe and complications more frequent in children older than 15 years old or younger than 1 year of age.
- Reactivation of varicella virus into herpes zoster ("shingles") later in life; chance of recurrent episodes of shingles associated with age, poor health, and varicella infection before 18 months of age.

## Risk of Serious Reaction From Being Vaccinated:

#### Varicella Vaccine:

- Shingles: at least 4 to 5 times less common after varicella vaccination than after natural disease (chickenpox). Also, usually very mild with no complications.
- Seizures caused by fever: less than 1 in 1000 people vaccinated.

#### Polio:

Up to 20,000 paralytic cases per year prior to vaccine. During 1970s several outbreaks in non-vaccinated populations, none in U.S. since 1979.

- Poliovirus is highly infectious: 90-100% of household contacts of an infected person will be infected with poliovirus.
- Permanent paralysis: 2 in 100.
- Death: 1 in 20 children and 1 in 4 adults with paralytic polio.

#### Polio Vaccine:

#### Oral Polio Vaccine (OPV):

 Permanent paralysis: 1 in 2,500,000 doses.

#### Inactivated Polio Vaccine (IPV):

 Severe allergic reactions very rare; no other severe reactions reported to date.

## 10. News Stories

#### Miss America's Hearing Loss

Miss America 1995, Heather Whitestone, is deaf. Ms. Whitestone had an infection with high fever in 1974, when she was 18 months old. A media item reported that an immunization had caused the fever and subsequent deafness, but this was a false report.

The real cause of her illness, according to her pediatrician, was *Haemophilus influenzae* type b (Hib) infection. She was treated with Gentamicin, one of the powerful antibiotic drugs used for this life-threatening infection. Unfortunately, hearing loss is one of the possible side effects of Gentamicin, particularly in infants. Deafness is also a common result of Hib meningitis infection.

Had Ms. Whitestone been born after 1985, she could have been immunized against the Hib infection and her disability prevented. Hib infections have been reduced by 90% since the vaccine was made available in 1985.

#### Polio: Her Story

In the 1940s, Kay, a young girl from a southwest Alaska village, would hunt, fish, chop wood, and go berry picking. One day while walking home from church, Kay tripped and fell, and by the time she got home, she was "real sick". She remained in bed for a month. Her leg curled up and she wasn't able to move it. Kay's family was finally able to get a plane to take her to the hospital where the examining doctor told her she had polio. He said, "There is nothing we can do for you; you'll never walk again," and he sent her home.

Her mother would warm up rocks three times a day and put them in a tub. Even though it was painful and throbbed when Kay moved, she would put her legs over the tub with a blanket covering them and stretch her curled leg while it was being warmed. Gradually, her leg straightened enough so that she could stand. Then began the slow process of learning to walk again. Eventually, Kay could push a chair across the floor while walking behind it. No longer could she go berry picking or chop wood. Instead, she stayed in the house and helped her mother with the dishes and preparing food for the winter.

Kay's brother and sister also were infected with the polio virus. Her brother was paralyzed but recovered; however, her nine-year-old sister became very ill and died.

Kay has weakness in her left leg that is worse in cold weather. She walks with a limp that even surgery has not cured and has suffered with leg and back pain most of her life. *Kay says, "It's better if children get the vaccine when they're small, so they won't get sick like I got sick."* 

#### A Mother and Child with Pertussis

Mary, a resident of Washington state, got pertussis (whooping cough) in 1990, a week before the birth of her second child. She caught it from the siblings of her son's friend, who visited one day while they had racking coughs.

After recognizing the telltale "whoop" in the cough, Mary discussed the issue with the friend's mother, who indicated she did not believe in immunizations.

Mary was seriously ill for six months and passed the disease on to her newborn son, who was hospitalized with pertussis at one week of age. (The child who originally infected Mary also was hospitalized for pertussis-related seizures.)

"My baby would cough 40 to 50 times in a row until he turned blue and threw up," Mary said. "I quite literally did not let go of him for the first six to nine months because I was afraid he was going to die."

The first four and a half years of his life have been full of bouts with infections and an uncontrollable cough. Many people who had been exposed to Mary and her son, especially young children and those over 60, had to be treated with antibiotics because of their increased risk of complications if they caught the disease.

The out-of-pocket cost to the family was extraordinary, even though both parents had excellent health insurance coverage. The community cost included many hours of investigation of contacts and the cost of the needed antibiotics ... and this was a healthy pregnancy.

#### Chickenpox: Not Always a Harmless Disease

On Christmas morning, 1999, one Alaska six year-old received an extra Christmas surprise – "chickenpox". Even though she continued to break out with more pox over the next couple of days, "Suzie" really didn't have very many spots or feel very bad. Then, on New Year's Eve, Suzie told her parents that her legs felt "wiggly". At first they didn't know what she meant, as she appeared fine; however, within a few hours, it became obvious that something was very wrong as she began having problems with coordination and walking. Suzie's parents rushed her to the emergency room and, after a battery of tests and brain scans, the doctors determined that she had developed encephalitis, a potentially life-threatening complication of chickenpox. The doctors then decided she needed to be sent from her small Southcentral Alaska community to Anchorage by air ambulance for treatment. Upon arriving in Anchorage, she was admitted to the pediatric intensive care unit of a local hospital for treatment.

"I will never forget what I was doing at the stroke of midnight, December 31, 1999." says Suzie's grandmother. "At that very minute I was hugging my granddaughter's mom as her baby was undergoing a spinal tap."

As the disease progressed, Suzie wasn't able to sit, crawl, stand, or walk, nor could she even turn over in bed or raise her head off the pillow. She had no coordination whatsoever. She also had double vision, along with bad bouts of nausea and vomiting.

"This was a tough time for Suzie's parents, too, as they had other children at home to care for, including two others that came down with chickenpox at the same time," Suzie's grandmother shares. "My granddaughter was very lucky-she eventually recovered completely from this serious complication of chickenpox."

Suzie also is fortunate that she did not have to be put on life support and that she only had to stay in the hospital about two weeks; it could have turned out much worse. Suzie's recovery wasn't without a lot of hard work by her parents, doctors, nurses, physical therapists, an occupational therapist, and speech therapists.

"It took a lot of work by a lot of people to help our granddaughter recover."



"Click here for more stories of unprotected people"

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#### Other Sources of Information

Alaska Immunization Hotline: (toll free) 1-888-430-4321, or in Anchorage: 269-8088

AK Info Line (Statewide Community Resources Information and Referral): 1-800-478-2221

CDC National Immunization Hotline (Spanish and English): 1-800-232-2522

State of Alaska, Department of Health and Social Services, Division of Public Health, Section of Epidemiology, Immunization Program: (907) 269-8000.

Vaccine Information Statements are available from the State of Alaska Immunization Program, most public health clinics and other immunization providers, and from the Centers for Disease Control and Prevention (CDC), or go to CDC's National Immunization Program website at: <a href="https://www.cdc.gov/nip">www.cdc.gov/nip</a>

#### Websites:

American Academy of Pediatrics: www.aap.org/family/vaccine.htm

Bill and Melinda Gates Children's Vaccine Program: www.childrensvaccine.org

Food & Drug Administration (FDA) vaccine safety and regulations: www.fda.gov/cber

Immunization Action Coalition: www.immunize.org

National Immunization Program: www.cdc.gov/nip

National Network for Immunization Information: www.immunizationinfo.org

Parents of Kids with Infectious Diseases (PKIDs): www.pkids.org

State of Alaska, Section of Epidemiology: www.epi.hss.state.ak.us

The Vaccine Page: www.vaccines.com

Vaccine Safety Information, CDC: www.cdc.gov/nip/vacsafe

\*\*If you or someone you know has experienced a serious reaction following vaccination, you can contact the health care provider who administered the vaccination and request that a VAERS report be completed (see Chapter 8 for details on VAERS), or call (800) 822-7967 to obtain a VAERS report form.

For information or questions about recommended **Adult Immunizations**, write the State of Alaska, Immunization Program; 3601 C Street, Suite 540; Anchorage, Alaska 99503, e-mail us at: immune@epi.hss.state.ak.us, or call (907) 269-8000.

This publication was produced by the Department of Health and Social Services, Division of Public Health, Section of Epidemiology, in order to provide parents with factual information about vaccines and vaccine-preventable diseases.

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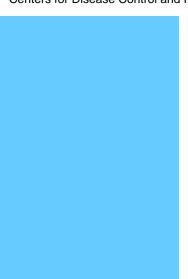
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### **Immunizations: What You Need To Know**

UPDATED

#### **Contents:**

- Why Children Should Be Immunized?
- Immunizations Do Work
- Immunizations Your Child Needs
- Immunizations Are Safe
- Current Immunization Schedule

Immunizations have been helping children for more than 50 years. But parents still have questions about why children need them, particularly since the diseases they prevent are often now uncommon! The following information will explain why immunizations are still so important. It also will help clear up some common misinformation many parents have.

### Why Children Should Be Immunized

"I've heard that vaccines are not needed because these diseases were disappearing even before the vaccines were developed."

This is not true. Many diseases do not occur or spread as much as they used to, thanks to better nutrition, less crowded living conditions, antibiotics, and, most importantly, vaccines. However, this does not mean that the bacteria and viruses that are responsible for these diseases have disappeared. Immunizations are still needed to protect children from these diseases.

For example, Haemophilus influenzae type b (Hib) diseases were a major problem a few years ago until the vaccine was developed for infants. Over several years, we went from 20,000 cases of Hib diseases to less than a few hundred. The vaccine is the only explanation for this decrease. Unvaccinated children are still at risk for Hib meningitis and other serious illnesses.

"Chickenpox is not a fatal disease, so that vaccine is not necessary."

<u>This is not true.</u> Each year, about 9,000 people are hospitalized for chickenpox. About 100 people die from the disease. The chickenpox vaccine will protect most children from getting chickenpox. Since the vaccine was licensed in 1995, millions of doses have been given to children in the United States. Many studies show the vaccine is safe and effective. Research is being done to see how long protection from the vaccine lasts and whether a person will need a booster shot in the future.

"I am breastfeeding so my child doesn't need immunizations."

<u>Immunizations are still needed.</u> While breastfeeding is the best nutrition for your baby, it does not prevent infections the way vaccines do. Your child may have fewer colds, but breastfeeding does not protect against many serious illnesses such as whooping cough, polio, and diphtheria like immunizations do.

"These diseases have been virtually eliminated from the United States, so my child doesn't need to be vaccinated."

Without immunizations at the right times, your child can still catch infectious diseases that may

cause high fever, coughing, choking, breathing problems, and even brain injury. These illnesses may leave your child deaf or blind or cause paralysis.

Immunizations have reduced most of these diseases to very low levels in the United States. However, some of these diseases are still common in other parts of the world. Travelers can bring these diseases into this country. Without immunizations, these infections could quickly spread here.

Immunizations also help people who cannot be vaccinated or who do not respond to vaccines. They can only hope that people around them are immunized.

### **Immunizations Do Work**

"I don't think vaccines even work. Most of the people who get these diseases have been vaccinated."

<u>Vaccines work very well.</u> Millions of children have been protected against serious illnesses such as polio, measles, and diphtheria because of vaccines.

There are always a few people who do not respond to vaccines. However, most childhood vaccines are 85% to 100% effective. Keep in mind that not getting vaccinated is 0% effective.

### Immunizations your child needs

Your child needs all of the following immunizations to stay healthy:

- MMR vaccine to protect against measles, mumps, and rubella (German measles)
- Polio vaccine to protect against polio
- DTaP (or DTP) vaccines to protect against diphtheria, tetanus (lockjaw), and pertussis (whooping cough)
- Hib vaccines to protect against *Haemophilus influenzae type b* (a major cause of spinal meningitis)
- Hepatitis B vaccine to protect against a virus that may cause liver disease
- Varicella vaccine to protect against chickenpox
- Hepatitis A vaccine in selected areas to protect against a serious liver disease caused by the hepatitis A virus.

### **Immunizations Are Safe**

"I've heard that it is unsafe to immunize a child who has a cold and fever.

Is this true?"

A child with a minor illness can safely be immunized. Minor illnesses include the following:

- low-grade fever
- ear infection
- cough
- runny nose
- mild diarrhea in an otherwise healthy child

"I've heard that some children have serious side effects from vaccines so they must not be very safe."

Reactions to vaccines may occur, but they are usually mild. Severe reactions to vaccines are very rare. Symptoms of a more serious reaction include the following:

- Very high fever
- Generalized rash
- Large amount of swelling at the point of injection

If any of these symptoms occur, call your pediatrician right away.

If your child experiences any side effects after a vaccination, talk to your pediatrician. Together you can decide whether your child should receive another dose of the same vaccine. Children with other health problems may need to avoid certain vaccines or get them later than usual. For example, children with certain types of cancers or problems with their immune systems should not get live virus vaccines like the MMR, varicella, or oral polio vaccines. For children with seizures, the pertussis part of the DTaP vaccine may need to be delayed. Ask your pediatrician when the vaccine can be given.

"I read that the DTP vaccine can cause Sudden Infant Death Syndrome (SIDS)."

There is no scientific evidence that links the DTaP or DTP shot and SIDS. This myth continues because the first dose is given at 2 months of age, when the risk of SIDS is greatest. However, these events are not connected.

"I saw on the news that there are "hot lots" of vaccines that are more dangerous than other lots."

The federal government set up the national Vaccine Adverse Events Reporting System (VAERS) to receive reports of vaccine reactions. People may think that if a large number of VAERS reports result from a particular batch of vaccine (a "hot lot"), then it must be dangerous. To date, no vaccine lot has ever been found to be unsafe based on VAERS reports.

Keep in mind, all vaccines are licensed by the Food and Drug Administration (FDA). Vaccine manufacturing facilities are licensed and regularly inspected. In addition, every vaccine lot is safety-tested by the manufacturer. The fact that a vaccine is still being used means that the FDA considers it safe.

"I've heard that giving a child more than one immunization at a time can be dangerous."

Studies and years of experience show that vaccines used for routine childhood immunizations can be safely given together. Side effects when multiple vaccines are given together are no greater than when each vaccine is given on separate occasions. Talk to your pediatrician if you are concerned about the number of vaccines your child is scheduled to receive.

"Immunizations hurt."

They may hurt a little, and your baby may cry for a few minutes. There may be some temporary swelling where your child was injected. However, protecting your child's long-term health is worth a few tears.

If your child is old enough to understand, explain that immunizations help prevent some very serious illnesses. Comfort and play with your child after the immunization. Acetaminophen can be used to help relieve some of the more common side effects, such as irritability and fever, but always check the dosage with your pediatrician.

"When should my child get immunized?"

<u>Children's immunizations need to be started when they are infants.</u> In fact, children should receive most of their immunizations during their first 2 years of life, starting at birth. Other immunizations are given before children go to school. Children who are behind on getting their

shots are at risk. They need to get immunized to catch up and be protected.

Older children and teens also need immunizations. Ask your pediatrician for the Recommended Childhood Immunization Schedule to see when your child needs to get immunized. Keep track of each immunization your child receives. Check with your pediatrician to make sure your child's immunizations are given on time and are up-to-date.

"Who should I call for more information?"

Call your pediatrician, local public health department, or community health center if

- Your child is sick and is scheduled to receive an immunization.
- You need information about immunizations or your child's health care needs.

Remember, immunizations are an important part of your child's total health care. Immunize your child on time, and keep your child's immunization record up-to-date. Make sure you take your child to the pediatrician's office or a health clinic on a regular basis.

### **Current Immunization Schedule**

Remember, immunization is a very important part of your child's total health care. Immunize your child on time, and keep your child's immunization record up-to-date. Make sure you take your child to the pediatrician's office or a health clinic on a regular basis so the doctor or clinic can get to know him or her. And be sure to get regular checkups, even when your child is healthy.

This information should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

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Every year, two to three million children die needlessly for the lack of new vaccines routinely given in North America, Europe, and Australia.



The Bill and Melinda Gates Children's Vaccine Program believes that it is a human right and a moral obligation that **all of the world's children** should have equal and timely access to new, life-saving vaccines.

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<u>Unprotected People</u> who have suffered from vaccine-preventable diseases

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The Hepatitis B Coalition, a program of the Immunization Action Coalition, promotes hepatitis B vaccination for all children 0-18 years; HBsAg screening for all pregnant women; testing and vaccination for high-risk groups; and education and treatment for people who are chronically infected with hepatitis B.

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New! What would happen if we stopped vaccinations? (8/00)

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Now available! influenza VIS translations - <u>Cambodian</u> - <u>Hmong</u> -<u>Laotian</u> - <u>Russian</u> - <u>Somali</u> (9/00)

Just out! <u>VACCINATE ADULTS!</u> spring/summer 2000 (9/20/00)

**Revised!** When do children and teens need vaccinations? **English** (9/00)

**Revised!** Immunizations...not just kids' stuff **English Spanish** (9/00)

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generous contributions from our members, generous educational grants provided by several foundations and companies, and the world-class expertise of our <u>Advisory Board</u>, we have been able to create, find, and distribute the most complete, up-to-date, and accurate supply and listing of immunization and hepatitis B resources available anywhere.

We would be delighted to have you join the thousands of people who support the Coalition. Help yourself to the unique resource materials we offer. All of our print materials are camera-ready, copyright-free, and reviewed by CDC for technical accuracy with the exception of opinion pieces written by non-CDC authors. Our materials are ready for you to make copies and distribute to your patients and staff. Be our guest!

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pneumococcal conjugate vaccine VIS

Haitian Creole VISs (9/5/00)

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• Influenza Vaccine 2000-2001:

<u>Delayed Vaccine Supply & Adjunct Recommendations</u> July 28, 2000 Recommendations July 27, 2000

• Gonorrhea, Chlamydia, and Syphilis in Alaska - 1999

Recommendations & Reports Volume 4 Number 5 (July 31, 2000)



• Escherichia coli O157 Outbreak - Kenai Peninsula:

Interim Report, <u>July 27, 2000</u> Interim Report, <u>July 21, 2000</u> Interim Report, <u>July 20, 2000</u>

• Proposed Revision of Immunization Requirements for Schools and Childcare Facilities

\*Bulletin No. 8 (May 2, 2000)

• Proposed Changes in Childhood Immunization Required Regulations

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Schedule for written and oral comments:

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(Find with the section 4 AAC 06.055, Immunizations, and 7 AAC 50, Health in Daycare and Full-Time Care Facilities)



Childhood Immunization Schedule 2000:

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### **An Overview of Vaccine Safety**

### **Introduction: The Importance of Vaccine Safety**

Perhaps the greatest success story in public health is the reduction of infectious diseases resulting from the use of vaccines. Routine immunization has eradicated smallpox from the globe and led to the near elimination of wild polio virus. Vaccines have reduced preventable infectious diseases to an all-time low and now few people experience the devastating effects of measles, pertussis and other illnesses. Prior to approval by the Food and Drug Administration (FDA), vaccines are extensively tested by scientists to ensure that they are effective and safe. Vaccines are the best defense we have against infectious diseases. However, no vaccine is 100% safe or effective. Differences in the way individual immune systems react to a vaccine account for rare occasions when people are not protected following immunization or when they experience side effects. 1,2,3

As infectious diseases continue to decline, some people have become less interested in the consequences of preventable illnesses like diphtheria and tetanus. Instead, they have become increasingly concerned about the risks associated with vaccines. After all, vaccines are given to healthy individuals, many of whom are children, and therefore a high standard of safety is required. Since vaccination is such a common and memorable event, any illness following immunization may be attributed to the vaccine. While some of these reactions may be caused by the vaccine, many of them are unrelated events that occur after vaccination by coincidence. Therefore, the scientific research that attempts to distinguish true vaccine side effects from unrelated, chance occurrences is crucial. This knowledge is necessary in order to maintain public confidence in immunization programs. As science continues to advance, we are constantly striving to develop safer vaccines and improve delivery in order to better protect ourselves against disease. This overview will focus on vaccine research, how vaccines are licensed, how safety is monitored, and how risks are communicated to the public. 1,2,3

### **Overview Outline**

Introduction: The Importance of Vaccine Safety

- 2. The National Childhood Vaccine Injury Act (NCVIA)
- 3. Monitoring Vaccine Safety: Pre-licensure
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### The National Childhood Vaccine Injury Act (NCVIA)

The topic of vaccine safety became prominent during the mid 1970's with increases in lawsuits filed on behalf of those presumably injured by the diphtheria, pertussis, tetanus (DPT) vaccine.<sup>4</sup> Legal decisions were made and damages awarded despite the lack of scientific evidence to support vaccine injury claims.<sup>4</sup> As a result of the liability, prices soared and several manufacturers halted production. A vaccine shortage resulted and public health officials became concerned about the return of epidemic disease. In order to reduce liability and respond to public health concerns, Congress passed the National Childhood Vaccine Injury Act (NCVIA) in 1986. This act was influential in many ways.

- (1) As a result of the NCVIA, the National Vaccine Program Office (NVPO) was established within the Department of Health and Human Services (DHHS). The responsibility of NVPO is to coordinate immunization-related activities between all DHHS agencies including the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA).
- (2) The NCVIA requires that all health care providers who administer vaccines containing diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, *Haemophilus influenzae* type b and varicella must provide a Vaccine Information Statement (VIS) to the vaccine recipient, their parent or legal guardian prior to each dose. A VIS must be given with every vaccination including each dose in a multi-dose series. Each VIS contains a brief description of the disease as well as the risks and benefits of the vaccine. VISs are developed by the CDC and distributed to state and local health departments as well as individual providers.
- (3) The NCVIA also mandates that all health care providers must report certain adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS). This system will be described in detail later in

the overview.

- (4) Under the NCVIA, the National Vaccine Injury Compensation Program (NVICP) was created to compensate those injured by vaccines on a "no fault" basis. This program will be described in detail later in the overview.
- (5) The NCVIA established a committee from the Institute of Medicine (IOM) to review the existing literature on vaccine adverse events (health effects occurring after immunization that may or may not be related to the vaccine). This group concluded that there are limitations in our knowledge of the risks associated with vaccines. Of the 76 adverse events they reviewed for a causal relationship, 50 (66%) had no or inadequate research. Specifically, IOM identified the following problems: (1) limited understanding of biological processes that underlie adverse events, (2) incomplete and inconsistent information from individual reports, (3) poorly constructed research studies (not enough people enrolled for a long enough period of time), (4) inadequate systems to track vaccine adverse events, and (5) few experimental studies published in the medical literature. Significant progress has been made over the past few years to better monitor adverse events and conduct research relevant to vaccine safety. 4,5

### **Monitoring Vaccine Safety: Pre-licensure**

Before vaccines are licensed by the FDA, they are extensively tested in the laboratory and in human beings to ensure their safety. First, computers are used to predict how the vaccine will interact with the immune system. Then researchers test the vaccine on animals including mice, guinea pigs, rabbits and monkeys. Once the vaccine successfully completes these laboratory tests, it is approved for use in clinical studies by the FDA. During clinical trials, the vaccine is tested on human beings. Participation in these studies is completely voluntary. Many individuals choose to contribute their time and energy for the advancement of science. Informed consent must be obtained from all participants before they become involved in research. This ensures that they understand the purpose of the study, potential risks and are willing to participate. Volunteers agree to receive the vaccine and undergo any medical testing necessary to assess its safety and efficacy.<sup>6</sup>

Vaccine licensure is a lengthy process that may take ten years or longer. The FDA requires that vaccines undergo three phases of clinical trials in human beings before they can be licensed for use in the general public. Phase one trials are small, involving only 20-100 volunteers, and last only a few months. The purpose of phase one trials is to evaluate basic safety and identify very common adverse events. Phase two trials are larger and involve several hundred participants. These studies last anywhere from several months to two years and collect additional information on safety and efficacy. Data gained from phase two trials can be used to determine the composition of the vaccine,

how many doses are necessary and a profile of common adverse events. Unless the vaccine is completely ineffective or causes serious side effects, the trials are expanded to phase three which involve several hundred to several thousand volunteers. Typically these trials last several years. Because the vaccinated group can be compared to those who have not received the vaccine, researchers are able to identify true side effects. 1,3,6,7,8

If the clinical trials demonstrate that the vaccine is safe and effective, the manufacturer applies to the FDA for two licenses, one for the vaccine (product license) and one for the production plant (establishment license). During the application process, the FDA reviews the clinical trial data and proposed product labeling. In addition, the FDA inspects the plant and goes over manufacturing protocols to ensure that vaccines are produced in a safe and consistent manner. Only after the FDA is satisfied that the vaccine is safe is it licensed for use in the general population.<sup>7</sup>

### **Monitoring Vaccine Safety: Post-licensure**

After a vaccine is licensed for public use, its safety is continually monitored. The FDA requires all manufacturers to submit samples from each vaccine lot prior to its release. In addition, the manufacturers must provide the FDA with their test results for vaccine safety, potency and purity. Each lot must be tested because vaccines are sensitive to environmental factors (like temperature) and can be contaminated during production. During the last ten years, only three vaccine lots have been recalled by the FDA. One lot was mislabeled and another was contaminated with particles during production. A third lot was recalled after the FDA discovered potential problems with the manufacturing process at a production plant.<sup>7</sup>

While clinical trials provide important information on vaccine safety, the data are somewhat limited because of the small number (hundreds to thousands) of study participants. Rare side effects and delayed reactions may not be evident until the vaccine is administered to millions of people. Therefore, the Federal Government has established a surveillance system to monitor adverse events that occur following vaccination. This project is known as the Vaccine Adverse Events Reporting System (VAERS). More recently, large-linked databases (LLDBs) containing information on millions of individuals have been created in order to study rare vaccine side effects. <sup>1,3</sup>

### The Vaccine Adverse Event Reporting System (VAERS)

The National Childhood Vaccine Injury Act of 1986 mandated that all health care providers report certain adverse events that occur following vaccination. As a result, the Vaccine Adverse Events Reporting System (VAERS) was established by the FDA and the Centers for Disease Control and Prevention (CDC) in 1990. VAERS provides a mechanism for the collection and analysis of adverse events associated with vaccines currently licensed in the United

States. Adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine. VAERS data are continually monitored in order to detect previously unknown adverse events or increases in known adverse events.<sup>1,9</sup>

Approximately 10,000-12,000 VAERS reports are filed annually, with 20% classified as serious (causing disability, hospitalization, life threatening illness or death). Anyone can file a VAERS report including health care providers, manufacturers, vaccine recipients or, when appropriate, parents/guardians. Those who have experienced an adverse reaction following immunization are encouraged to seek help from a health care professional when filling out the form. VAERS forms can be obtained in several ways. Each year the form is mailed to more than 200,000 physicians specializing in pediatrics, family practice, internal medicine, infectious diseases, emergency medicine, obstetrics and gynecology. In addition, copies are sent to health departments and clinics that administer vaccines. The VAERS form requests the following information: the type of vaccine received, the timing of vaccination, the onset of the adverse event, current illnesses or medication, past history of adverse events following vaccination and demographic information about the recipient (age, gender, etc.). The form is pre-addressed and stamped so it can be mailed directly to VAERS. To request a VAERS form or assistance in filling in out, call 1-800-822-7967.1,9

A contractor, under the supervision of FDA and CDC, collects the information and enters it into a database. Those reporting an adverse event to VAERS receive a confirmation letter by mail indicating that the form was received. This letter will contain a VAERS identification number. Additional information may be submitted to VAERS using the assigned identification number. Selected cases of serious adverse reactions are followed up at 60 days and one year post-vaccination to check the recovery status of the patient. The FDA and CDC have access to VAERS data and use this information to monitor vaccine safety and conduct appropriate research studies. VAERS data (minus any personal information) is also available to the public. <sup>1,9</sup>

While VAERS provides useful information on vaccine safety, the data are somewhat limited. Specifically, judgments about causality (whether the vaccine was truly responsible for an adverse event) cannot be made from VAERS reports because of incomplete information. VAERS reports often lack important information such as laboratory results. As a result, researchers have turned more recently to large-linked databases (LLDBs) in order to study vaccine safety. LLDBs provide scientists with access to the complete medical records of millions of individuals receiving vaccines (all identifying information is deleted to protect the confidentiality of the patient). One example of a LLDB is the Vaccine Safety Datalink (VSD) project described below, which is coordinated by the CDC. Studies conducted using LLDBs, like the VSD, are also known as post-marketing research or phase four clinical trials. <sup>1</sup>

#### The Vaccine Safety Datalink (VSD) Project

The gaps that exist in the scientific knowledge of rare vaccine side effects prompted the CDC to develop the Vaccine Safety Datalink (VSD) project in 1990. This project involved forming partnerships with four large health maintenance organizations (HMOs) to continually monitor vaccine safety. VSD is an example of a large-linked database (LLDB) and includes information on more than six million people. All vaccines administered within the study population are recorded. Available data include vaccine type, date of vaccination, concurrent vaccinations (those given during the same visit), the manufacturer, lot number and injection site. Medical records are then monitored for potential adverse events resulting from immunization. The VSD project allows for planned vaccine safety studies as well as timely investigations of hypotheses. At present, the VSD project is examining potential associations between vaccines and 34 serious conditions. The database is also being used to test new vaccine safety hypotheses that result from the medical literature, VAERS, changes in the immunization schedule or from the introduction of new vaccines. This project is a powerful and cost-effective tool for the on-going evaluation of vaccine safety. 1,10

### The Vaccine Injury Compensation Program

In order to reduce the liability of manufacturers and health care providers, the National Childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program (NVICP). This program is intended to compensate those individuals who have been injured by vaccines on a "no-fault" basis. No fault means that people filing claims are not required to prove negligence on the part of either the health care provider or manufacturer to receive compensation. The program covers all routinely recommended childhood vaccinations. Settlements are based on the Vaccine Injury Table which summarizes the adverse events caused by vaccines. This table was developed by a panel of experts who reviewed the medical literature and identified the serious adverse events that are reasonably certain to be caused by vaccines. Examples of table injuries include anaphylaxis (severe allergic reaction), paralytic polio and encephalopathy (general brain disorder). The Vaccine Injury Table was created to justly compensate those injured by vaccines while separating out unrelated claims. As more information becomes available from research on vaccine side effects, the Vaccine Injury Table is updated. 11,12

Individuals and their families can qualify for compensation in three ways. First, is to show that an injury found on the Vaccine Injury Table occurred in the appropriate time interval following immunization. The other two ways to qualify include proving that the vaccine caused the condition or demonstrating that the vaccine worsened or aggravated a pre-existing condition. <sup>11,12</sup>

The vaccine injury compensation process begins when an individual files a petition with the United States Court of Federal Claims. At that point, a physician from the program reviews the petition to determine whether it meets the criteria for compensation. This recommendation is not binding. A Court attorney then reviews the case and makes an initial decision for or against entitlement to compensation. Decisions may be appealed to the Court of Federal Claims, and then to the Federal Circuit Court of Appeals. This process occurs at no cost to the individual filing the claim. NVICP is coordinated by the Department of Health and Human Services and the Department of Justice. For more information on the program or for assistance in making a claim, call 1-800-338-2382. 11,12

### **Improvements in Vaccine Safety**

In the last decade, numerous changes in vaccine production and administration have reduced the number of adverse events and resulted in safer vaccines. A more purified acellular pertussis (aP) vaccine has been licensed for use and is replacing the whole-cell pertussis vaccine used in DTP (diphtheria, tetanus, pertussis vaccine). Several studies have evaluated the safety and efficacy of DTaP as compared to DTP and have concluded that DTaP is effective in preventing disease and that mild side effects and serious adverse events occurred less frequently when the DTaP vaccine was given.<sup>3</sup> Recent changes in the schedule of polio vaccines have also resulted in fewer reports of serious side effects. In 1997, the Advisory Committee on Immunization Practice recommended a change in the vaccination schedule to include sequential administration of inactivated polio vaccine (IPV) and oral polio vaccine (OPV).<sup>13</sup> The new sequential schedule is expected to produce a high level of individual protection against the disease caused by wild polio virus, while reducing by 50 to 70% vaccine-associated paralytic polio (VAPP) that occurs in 8-10 people a year who receive OPV.<sup>14</sup>

### **Risk Communication**

At some point, almost every person in the United States is vaccinated. Therefore, many individuals question how vaccines are made, if they are effective and whether they are safe. People seek answers to these questions from a wide variety of sources including family, friends, health care providers, the Internet, television and medical literature. The information they receive is complex and, at times, inaccurate or misleading. Therefore, health professionals have a responsibility to provide accurate, understandable information and to handle vaccine safety concerns appropriately. As mentioned previously, the NCVIA requires all health care providers who administer vaccines to discuss the potential risks and benefits of immunization. In these situations, risk communication is a necessary skill.

Risk communication involves a dynamic exchange of information between

individuals, groups and institutions. This information must acknowledge and define the risks associated with vaccination in a way the public can understand. This is difficult given the current environment where few people experience the devastation of vaccine-preventable diseases. It is further complicated by the fact that immunization is associated with some degree of personal discomfort when needles are used to administer vaccines.<sup>1</sup>

In 1996, the Institute of Medicine's Vaccine Safety Forum held a workshop on risk communication and vaccination. Three key concepts emerged:

"First, risk communication is a dynamic process in which many participate, and these individuals are influenced by a wide variety of circumstances, interests, and information needs. Effective risk communication depends on the providers' and recipients' understanding more than simply the risks and benefits; background experiences and values also influence the process.<sup>18</sup> Good risk communication recognizes a diversity of form and context needs in the general population.

Second, the goal that all parties share regarding vaccine risk communication should be informed decisionmaking. Consent for vaccination is truly 'informed' when the members of the public know the risks and benefits and make voluntary decisions.

Finally, there is often uncertainty about estimates of the risk associated with vaccination. Risk communication is more effective when this uncertainty is stated and when the risks are quantified as much as science permits. Trust is a key component of the exchange of information at every level, and overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown of trust among public health officials, vaccine manufacturers, and the public. Continued research to improve the understanding of vaccine risks is critical to maximizing mutual understanding and trust." <sup>19</sup>

Several resources are available to address the risks and benefits of vaccination. Federal law requires all health care providers who administer vaccines in the United States to provide Vaccine Information Statements (VISs) to vaccine recipients (or their parent/guardian) prior to each dose being administered. VISs are developed by CDC and contain information on the disease as well as the risks and benefits associated with immunization. These documents, and others, can be obtained from the National Immunization Hotline 1-800-232-2522 or from the National Immunization Program's Web Page.

### **Conclusion: The Future of Vaccine Safety**

The importance of vaccine safety will continue to grow throughout the twenty-first century. The development and licensure of new vaccines will add to the already complicated immunization schedule. Scientists may also perfect new ways of administering immunizations including edible vaccines and

needleless injections. None the less, however they are formulated or delivered, vaccines will remain the most effective tool we possess for preventing disease and improving public health in the future.

### **Additional Resources**

### **General Vaccine Safety**

Epidemiology and Prevention of Vaccine-Preventable Diseases, Vaccine

Safety (Chapter 15)

Vaccine Safety: Current and Future Challenges

Vaccine Safety Resource List

Institute of Medicine, Vaccine Safety Forum (1997)

World Health Organization's Web Page on Vaccine Safety

National Vaccine Program Office's Web Page on Vaccine Safety

#### **Vaccine Adverse Events**

<u>Institute of Medicine Review of Vaccine Adverse Events</u>
<u>Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines</u>
(1991)

<u>Institute of Medicine, Adverse Events Associated with Childhood Vaccines:</u> Evidence Bearing on Causality (1994)

#### **Vaccine Licensure**

FDA Licensure of Vaccines

### **Monitoring Vaccine Safety**

The Complicated Task of Monitoring Vaccine Safety

### The Vaccine Adverse Events Reporting System (VAERS)

The Vaccine Adverse Events Reporting System (VAERS)

FDA's Web Site on VAERS

VAERS Table of Reportable Events

**VAERS** Form

### The Vaccine Safety Datalink (VSD) Project

Vaccine Safety Datalink Project: Current and Completed Studies

Vaccine Safety Datalink References

Vaccine Safety Datalink Project: A New Tool for Improving Vaccine Safety

Monitoring in the United States

**National Vaccine Injury Compensation Program (NVICP)** 

#### **NVICP's Web Site**

#### **Risk Communication**

Institute of Medicine, Risk Communication and Vaccination (1997)

Current Vaccine Information Statements (VISs)

Questions and Answers about Vaccine Information Statements (VISs)

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